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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,260	11/14/2003	Signe Thorning Mejlhede	P69290US0	8054
136	7590	09/13/2007		
JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			EXAMINER HEITBRINK, JILL LYNNE	
			ART UNIT 1732	PAPER NUMBER
			MAIL DATE 09/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/712,260

Applicant(s)

MEJLHEDE ET AL.

Examiner

Jill L. Heitbrink

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 16, 2007 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-10 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9, 10 and 23 of copending Application No. 10/578,972. Although the conflicting claims are not

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identical, they are not patentably distinct from each other because the use of the catheter with an introducer needle (in 10/578,972 claim 1) does not limit the method of molding the one-piece soft needle catheter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-10 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fentress et al. Pub. No. 2005/0033237 taken together with either McFarlane Pat. No. 4,404,159 or Hoef Pat. No. 3,694,280.

6. Fentress [0018] discloses a process essentially equivalent to that claimed except for a cylindrical portion of the tube shaped flexible part being formed distal from the hub. The draft of the internal surface adds in the removal of the core from the mold, see paragraphs [0058], [0063] and [0130]. McFarlane (col. 1, lines 18-28) and Hoef (col. 2, lines 3-15) each teach that the tip of the catheter should tightly fit the needle so as not cause skin to enter between the catheter tip and the needle. It would have been obvious to a person when forming the tip of Fentress to the desired shape [0057] to form the tube-shaped flexible part with a cone-shaped portion (draft) extending between

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the hub cavity and a cylindrical portion since the cylindrical portion would provide a tight fit between the needle and the catheter during use.

7. Claims 1-10 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braun Pat. No. 3,385,553 in view of Fentress et al. Pub. No. 2005/0033237 taken together with either McFarlane Pat. No. 4,404,159 or Hoef Pat. No. 3,694,280.

8. Braun discloses a method for one-piece injection molding of a flexible (soft) catheter (col. 1, line 34). The molten polymer is feed into a mold (Fig. 4) having a core (24 and 25) forming the interior of the catheter. The catheter formed has a hub (reinforcement 3 and expanded portion 4) and a tube-shaped flexible part (cannula 1). The step of feeding includes using a core having a cone-shaped part (24) that extends from the hub cavity at least up to the tube-shaped cavity. Fentress et al. teaches the draft of the internal surface adds in the removal of the core from the mold, see paragraphs [0058], [0063] and [0130]. It would have been obvious to a person of ordinary skill in the art to extend the cone-shaped part of the core into the tube-shaped cavity of Braun so as to provide a smooth transition to the needle portion 25 and to provide a draft along the needle portion to ease the removal of the core. McFarlane (col. 1, lines 18-28) and Hoef (col. 2, lines 3-15) each teach that the tip of the catheter should tightly fit the needle so as not cause skin to enter between the catheter tip and the needle. The draft of the core would not extend to the end of the catheter since this would cause skin to enter between the catheter and the needle.

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9. Claims 1-4 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gawreluk et al. Pat. No. 6,887,417 taken together with Gellmann Pat. No.

5,057,083.

10. Gawreluk discloses a process for one-piece injection molding a catheter introducer which includes a hub 32 and a tube shaped flexible part 30. The polymer is feed into a mold having a core. Gawreluk (col. 7, lines 1-37) discloses that the sleeve 30 may have a slight draft angle. A core pin 140 is used to form the inside of the sleeve including the draft within the tube shaped flexible part. Gawreluk does not disclose that the tip of the tube shaped part has an inside cylindrical shape formed by the core pin. Gellmann (col. 3, lines 31-35) teaches the shaping of the flexible tube shaped part with a tapered portion and a cylindrical portion 25. It would have been obvious to provide the core of Gawreluk with a cone shaped portion (draft portion) and a cylindrical portion since the cylindrical portion would provide a close fit about the cannula during use (col. 1, lines 41-50 of Gawreluk).

11. Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of the above rejection as applied to claim 1 above, and further in view of Goral et al. Pat. No. 6,630,086.

12. Goral (col. 9, lines 61-62) teach that the mold halves can be mated longitudinally or vertically. It would have been obvious to a person of ordinary skill in the art to

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separate the mold along the axis or perpendicular to the tube in any of the primary references since these are known alternatives in the art of molding catheters.

13. Goral teaches the selection of materials for the hub and tube equivalent to the in claims 7, 8 and 9. The process in Goral is gas assist injection molding rather than injection molding with a core. It would have been obvious to a person of ordinary skill in the art to use the material of Goral in the injection molding process of the primary reference since these material are known to be injection moldable and are known to be desired in medical catheters.

Response to Arguments

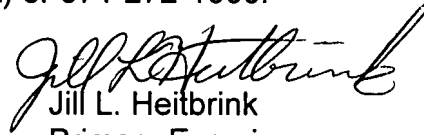
14. Applicant's arguments with respect to claims 1-10 and 24 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jill L. Heitbrink whose telephone number is (571) 272-1199. The examiner can normally be reached on Monday-Friday 9 am -2 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jill L. Heitbrink
Primary Examiner
Art Unit 1732

jlh